



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,509	12/07/2001	Marie-Claude Gingras	HO P02046US1	8559

26271 7590 11/05/2003  
FULBRIGHT & JAWORSKI, LLP  
1301 MCKINNEY  
SUITE 5100  
HOUSTON, TX 77010-3095

EXAMINER
----------

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 11/05/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/021,509

Applicant(s)

GINGRAS ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendments, filed 5/02/03 (Paper No: 7), is acknowledged.

Claims 1-38 are pending.

#### ***Restriction Requirement***

For examination purposes the following is noted: claims 24 and 25 recited as being dependent upon base claim 32. However, in consistence with the disclosure of the specification claims 24 and 25 should be dependent upon base claim 23. Therefore, the restriction has been set forth accordingly.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-17, drawn to a method of modulating an immune response; a method of decreasing myeloid cell activation and a method of modulating an inflammatory response each comprising the step of administering a compound to an animal to decrease the activity of DAP12/TREM-1 complex, classified in Class 424, subclass 185.1.
  - II. Claim 18, drawn to a method of treating inflammation comprising the step of administering a pharmaceutical carrier admix with polypeptide of SEQ ID NO:2 or a functional equivalent thereof, classified in Class 424, subclass 185.1.
  - III. Claims 19-21, drawn to a method of treating autoimmune disorder comprising the step of administering a polypeptide of SEQ ID NO:2 or a functional equivalent thereof, classified in Class 424, subclass 185.1.
  - IV. Claim 22, drawn to a method of modulating tissue healing/repair comprising the step of administering a polypeptide of SEQ ID NO:2 or a functional equivalent thereof, classified in Class 424, subclass 185.1.
  - VI. Claims 23-24, drawn to a method of modulating myeloid cell mediated tumor immunotherapy comprising the step of administering a compound to decrease the level of TREM-1 splice variant, wherein said compound is antibody classified in Class 424, subclasses 130.1 and 139.1.

Art Unit: 1644

- V. Claims 23, 25, drawn to a method of modulating myeloid cell mediated tumor immunotherapy comprising the step of administering a compound to decrease the level of TREM-1 splice variant, wherein said compound is antisense molecule of TREM-1 splice variant, classified in Class 424, subclass 184.1.
- VI. Claims 26, 27, 29 and 30, drawn to a method of diagnosing an inflammatory response, comprising isolating macrophage from the tissue sample and measuring the levels of TREM-1 protein in the macrophages, classified in Class 435, subclasses 7.1 and 326.
- VII. Claim 26 and 28- 30, drawn to a method of diagnosing an inflammatory response, comprising isolating neutrophils from the tissue sample and measuring the levels of TREM-1 protein in the neutrophils, classified in Class 435, subclasses 7.1 and 326.
- VIII. Claim 31, drawn to a method of diagnosing an inflammatory response, comprising collecting a blood samples and measuring the levels of TREM-1 splice variant protein in the sample, classified in Class 435, subclasses 7.1 and 326.
- IX. Claims 32-34, drawn to a method of diagnosing an inflammatory response, comprising collecting a blood samples and measuring the levels of TREM-1 protein in the monocytes and neutrophils and measuring the levels of TREM-1 splice variant protein in blood sample, classified in Class 435, subclasses 6, 7.1 and 326.
- X. Claims 35-38, drawn to a method of modulating cellular activity and phagocytic activity, comprising a step of administering to the subject a compound to decrease the activity of DAP12/TREM-1 complexes classified in Class 424, subclasses 185.1 and 93.7.

3. Groups I- X are different methods. These inventions are different with respect to ingredients, method steps, and in etiologies and therapeutic endpoints of pathological conditions which require non-coextensive searches ; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the distinct method steps and etiologies and therapeutic endpoints of pathological conditions. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

5. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. If Group I is elected, applicant is required to elect a specific method of modulating an inflammatory response, wherein the specific disease or condition is selected from the group recited in claim 15.

These species are distinct because a specific method of modulating an inflammatory response, wherein the specific disease or condition is selected from the group recited in claim 15 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

7. If Group III is elected, applicant is required to elect a specific method of treating autoimmune disorder, wherein the specific disorder is selected from the group recited in claim 20.

These species are distinct because a specific method of treating autoimmune disorder, wherein the specific disorder is selected from the group recited in claim 20 differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1644

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

A telephone call was made to Melissa W. Acosta on 10/24/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 3, 2003

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600